REMARKS

Claims 1 through 24 are pending in the application.

Claims 1 and 10 have been amended to reflect that the inventive cholesterol-reducing agents advantageously include from 1 to 15 g of carob product. Support for this amendment can be found in the Application-as-filed, for example on Page 16, lines 23 through 24.

Claims 1 and 10 have also been amended to emphasize advantageous embodiments in which DHA alone induces at least a 10% reduction in cholesterol. Support for this amendment can be found in the Application-as-filed, for example on Page 10, lines 1 through 4 and on Page 11, lines 19 through 23.

Claim 20 has been canceled, as its subject matter has been incorporated into Claim 1.

Applicants respectfully submit that this response does not raise new issues, but merely places the above-referenced application either in condition for allowance, or alternatively, in better form for appeal. Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

The Claimed Invention is Patentable in Light of the Art of Record

Claims 1 through 24 stand rejected over United States Patent No. 5,856,313 ("US 313") to Marco et al. in combination with United States Patent No. 5,502,077 ("US 077") to Breivik et al. and McKenney (Lipid Management).

It may be useful to briefly consider the invention before addressing the merits of the rejection.

As noted in Applicants' Amendment of October 6, 2006, a number of therapeutic active compounds are prescribed for treating high cholesterol, including statins and the like. All of such therapeutic active compounds must be taken under medical supervision and monitoring. Furthermore, to achieve the therapeutic aims, sometimes considerable concentrations have to be used.

A number of food components are known to positively effect cholesterol, as well. Unfortunately, the effects which can be achieved with such food components are significantly below those which are achieved using therapeutic active compounds. Furthermore, such food components are similarly taken in significant quantities to achieve therapeutic benefit. For food components such as fiber, excessive consumption may induce unwanted side effects.

In addition, antagonistic actions have been found between combined food components. The combination of water insoluble carob fiber and viscous dietary fiber derived from carob seed meal has been shown to be detrimental to blood cholesterol levels, for example. (The Examiner's attention is kindly directed to the Application-as-filed at Page 5, lines 4 through 16).

Altogether unexpectedly, Applicants have found that a combination of carob product, n-3 fatty acid and cholesterol-reducing active compound provides a synergistic reduction in cholesterol levels. The synergistic benefits of the inventive cholesterol-reducing compounds allows far less of the components to be used, decreasing unwanted side effects. The inventive cholesterol-reducing compounds may advantageously include from 1 to 15 gm of carob product, for example.

Surprisingly, the inventive synergistic cholesterol-reducing agents may further beneficially incorporate a particular n-3 fatty acid which was heretofore understood to have no

effect on blood pressure, as expressly evidenced by US 077. More particularly, the inventive cholesterol-reducing agents have been found to provide a reduction of total cholesterol of at least 10% for embodiments in which the n-3 fatty acid consists of DHA alone, as reflected in the claims as-amended.

Accordingly, the claims are directed to cholesterol-reducing agents that include from 1 to 15 g of at least one carob product, at least DHA as an n-3 fatty acid and at least one cholesterol-reducing active compound. Surprisingly, inventive agents incorporating DHA alone induce a reduction of total cholesterol of at least 10%, as further recited in the claims as-amended.

The cited references do not teach or suggest the claimed invention.

US 313 is merely directed to methods of making carob fiber. US 313 discloses a nine step method of extracting water insoluble carob fiber from carob pods. (Col. 1, line 53 – Col. 3, line 44). US 313 merely generically indicates that carob fiber of indeterminant length, ingested alone, has a hypocholesterolaemiant effect when provided as 5% of an animal's diet. (Col. 5, lines 1 - 28).[1]

US 313 thus does not teach or suggest the claimed invention.

Applicants respectfully reiterate that US 313 does not teach or suggest the recited synergistic cholesterol-reducing agent that includes a combination of carob fiber product, n-3 fatty acid and at least one cholesterol-reducing active compound which provides a greater reduction in cholesterol level than the sum of the effects when the carob, n-3 fatty acid or cholesterol-reducing active compound are administered alone.

---

[1] Applicants respectfully reiterate that the USDA's recommended 2000 calorie diet contains approximately 466 g of nutrients. Accordingly, US 313's percentage converts into a daily weight dosage of approximately 23 g of fiber per day.

Applicants further respectfully reiterate that, in contrast to the urgings of the Office Action, the recited components provide more than an "additive effect," as indicated numerous times in the Application-as-filed. MPEP 2144.09 (presence of synergy rebutting *prima facie* obviousness rejection). In particular, the Application-as-filed on Page 6, lines 33 through 35 notes a "synergistic reduction" in cholesterol level, and on Page 18, lines 9 through 15, notes that the intake of the inventive agent leads to a "markedly stronger reduction" in cholesterol than the sum of the individual components. Applicants further respectfully submit that constructive reduction to practice is sufficient under United States practice and that working examples are not required.

Nor does US 313 teach or suggest the administration of the advantageous inventive agent containing carob in a daily dose ranging from 1 to 15 g, as recited in the claims as amended. Considered in its entirety, US 313 instead expressly teaches the administration of carob in significantly higher dosages, which there would have been no motivation to have lowered.

And US 313, altogether silent as to fatty acids, most certainly does not teach or suggest the recited cholesterol-reducing agents in which the agent provides a reduction of total cholesterol of at least 10% when the n-3 fatty acid consists of DHA alone.

Accordingly, Applicants respectfully submit that US 313 does not teach or suggest the claimed invention, considered either alone or in combination with the remaining art of record.

US 077 does not cure the deficiencies in US 313.

The entire impetus of US 077 is the provision of a mixture of DHA and EPA fatty acids. (Col. 2, lines 50 – 56 and lines 63 - 67). In contrast to the urgings of the Office Action, US 077 expressly indicates that "[t]o our knowledge there is nothing to suggest that DHA alone has any effect on the blood pressure." (Col. 2, lines 26 – 27). In fact, US 077 teaches that EPA alone

does not have a significant effect. (Col. 2, lines 1 – 2). US 077 thus requires a mixture of DHA and EPA fatty acids, present in a specific weight ratio. (Col. 2, lines 50 – 53).

US 077 goes to significant lengths to ensure provision of a DPH/EPA mixture. In particular, the DHA/EPA fatty acid mixture is formed by subjecting marine oil to numerous processes, including molecular distillation. (Col. 3, lines 24 – 29). Molecular distillation is used to "upgrade" either the DHA or EPA fraction (as appropriate) into the required 1:1 to 2:1 ratio. (Col. 3, lines 60 – 65). US 077 recommends a dose of from 1000 mg to 10,000 mg of its mixture daily. (Col. 3, lines 43 – 46).

Applicants respectfully reiterate that US 077 likewise fails to teach or suggest the recited cholesterol-reducing agents that include a combination of carob product, n-3 fatty acid and cholesterol-reducing active compound and provide a synergistic reduction in cholesterol level. At the time the instant Application was filed, US 077 touted an altogether different combination, i.e. a combination of fatty acids alone, as providing advantageous results.

And US 313, expressly indicating that DHA alone is ineffective, most certainly does not teach or suggest the recited cholesterol-reducing agents in which the agent provides a reduction of total cholesterol of at least 10% when the n-3 fatty acid consists of DHA alone.

Nor does US 077 teach or suggest the advantageous agents of Claim 5, in which the synergistic effect is imparted by a single n-3 fatty acid having a chain length > C12. Applicants respectfully reiterate that US 077, considered in its entirety at the time the instant Application was filed, clearly indicates that all fatty acids having chain lengths of less than 20 are removed from its marine oil.

Thus US 077 most certainly does not teach or suggest such agents in which the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 8. As noted above, considered in its entirety, US 077 clearly taught that DHA alone was an altogether

ineffective treatment. Thus there would have been absolutely no expectation of success for cholesterol-reducing agents including DHA alone at the time the instant Application was filed.

US 077, directed solely to fatty acid mixtures including EPA, likewise can not teach or suggest the advantageous inventive agents in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16, 19-docosahexaenoic acid (DHA), as recited in Claim 22.

Nor does US 077, solely directed to method of processing marine oil to produce its mixtures having a requisite weight range of EPA to DHA, teach or suggest the advantageous inventive agents in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms, as recited in Claim 21. In contrast to the opinion urged within the Office Action, the source of fatty acid would be expected to affect the overall fatty acid composition.

And US 077 most certainly does not teach or suggest the synergy provided by the advantageous administration of an agent containing n-3 fatty acid in a daily dose ranging from 50 mg to 600 mg, as recited in Claim 23. US 077 instead teaches away from such embodiments by recommending a daily administration of up to 10,000 mg of its fatty acid mixture.

Accordingly, Applicants respectfully submit that US 077 does not teach or suggest the claimed invention, considered either alone or in combination with the remaining art of record.

Lipid Management does not cure the deficiencies in either of the foregoing references.

Lipid Management merely presents an overview of various cholesterol-reducing drugs, including statins, bile acid resins and the like. Lipid Management generically notes that diets including omega-3 fatty acids and fiber are beneficial. In contrast to the opinion urged within the

Office Action, Lipid Management merely discloses use of drug therapy for patients unable to reach the desired LDL-C goal through diet. (S300). The only combination expressly taught by Lipid Management is a combination of cholesterol-reducing drugs. (S303).

Applicants thus respectfully reiterate that Lipid Management fails to teach or suggest the recited synergistic cholesterol-reducing agents that include a combination of carob product, n-3 fatty acid and cholesterol-reducing active compound which provide a greater reduction in cholesterol level than the sum of the effects when the carob, n-3 fatty acid or cholesterol-reducing active compound are administered alone. Applicants further respectfully reiterate that Lipid Management instead teaches away from the beneficial synergies imparted by carob and fatty acid by expressly touting drug combinations as providing advantageous results.

Nor does Lipid Management, generically referencing "diet", teach or suggest the administration of the advantageous inventive agent containing carob in a daily dose ranging from 1 to 15 g, as recited in the claims as amended.

And Lipid Management, likewise generically referencing fatty acids, most certainly does not teach or suggest the recited cholesterol-reducing agents in which the agent provides a reduction of total cholesterol of at least 10% when the n-3 fatty acid consists of DHA alone.

Lipid Management thus most certainly does not teach or suggest such agents in which the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 8.

Lipid Management likewise can not teach or suggest the advantageous inventive agents in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 22.

Nor does Lipid Management, broadly recommending fatty acids from fish, teach or suggest the advantageous inventive agents in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms, as recited in Claim 21.

Lipid Management likewise fails to teach or suggest the synergy provided by the advantageous administration of an agent containing n-3 fatty acid in a daily dose ranging from 50 mg to 600 mg, as recited in Claim 23.

And Lipid Management most certainly does not teach or suggest advantageous inventive agents in which the cholesterol-reducing active compound is present at 10 to 50% of the dosage which would be recommended in the absence of carob product and n-3 fatty acid, as recited in Claim 24. As noted above, Lipid Management instead teaches away from the synergistic inventive combination of particular food components and cholesterol-reducing active compound by touting the benefits of drug combinations.

Accordingly, Applicants respectfully submit that Lipid Management does not teach or suggest the claimed invention, considered either alone or in combination with the remaining art of record.

Applicants respectfully submit that there would have been no motivation to have combined US 313, US 077 and Lipid Management. US 313 is directed to methods of making carob flour. US 077 is directed to methods by which to produce a particular fatty acid mixture from marine oil. Lipid Management is merely an overview of various cholesterol-reducing drugs. These are altogether different fields of endeavor and problems solved, to say the least.

The Office Action is clearly indulging in an impermissible hindsight analysis by picking and choosing particular elements from the prior art while ignoring others. In particular, US 313

recommends consumption of significant quantities of fiber daily. US 077 clearly indicates that DHA alone is ineffective.

Consequently, even if combined (which Applicants did not), the claimed invention would not result.

The combination specifically fails to teach or suggest that the recited synergistic cholesterol-reducing agents including a combination of carob product, n-3 fatty acid and cholesterol-reducing active compound would provide a greater reduction in cholesterol level than the sum of the effects when the carob, n-3 fatty acid or cholesterol-reducing active compound are administered alone.

Nor does the combination teach or suggest the administration of the advantageous inventive agent containing carob in a daily dose ranging from 1 to 15 g, as recited in the claims as-amended. Lipid Management merely encourages consumption of fruits and vegetables. US 313 expressly teaches the use of much greater amounts of carob. Applicants respectfully submit that the Office Actions' urgings of the recited range as "optimization" constitute an impermissible hindsight analysis in light of the express teachings of US 313.

And the combination most certainly does not teach or suggest the recited cholesterol-reducing agents in which the agent provides a reduction of total cholesterol of at least 10% when the n-3 fatty acid consists of DHA alone. Applicants likewise respectfully submit that the Office Actions' urgings regarding the use of the recited DHA alone in reducing cholesterol constitute an impermissible hindsight analysis in light of US 077's express teaching that DHA alone has no effect. Hence the benefit of DHA as the sole fatty acid was not a "known property" at the time the instant Application was filed.

The combination thus most certainly does not teach or suggest such agents in which the single n-3 fatty acid is all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim

8. In that regard, Applicants respectfully submit that US 077 clearly indicates that the only "value" DHA has in treating hypertriglyceridemia is in combination with EPA.

The combination likewise can not teach or suggest the advantageous inventive agents in which the n-3 fatty acid consists of one or more of: all-cis-9,12,15-octadecatrienoic acid (ALA), all-cis-6,9,12,15-octadecatetraenoic acid, all-cis-11,14,17-eicosatrienoic acid, all-cis-13,16,19-docosatrienoic acid, all-cis-7,10,13,16,19-docosapentaenoic acid (DPA) and all-cis-4,7,10,13,16,19-docosahexaenoic acid (DHA), as recited in Claim 22.

Nor does the combination teach or suggest the advantageous inventive agents in which the n-3 fatty acid is derived from vegetable oil or oils from microorganisms, as recited in Claim 21. In contrast to the urgings of the Office Action, US 077 and Lipid Management are directed to fatty acids obtained from fish or fish oils. As evidenced by US 077, the fatty acid source would clearly be expected to influence the fatty acid composition obtained therefrom.

The combination likewise fails to teach or suggest the synergy provided by the advantageous administration of an agent containing n-3 fatty acid in a daily dose ranging from 50 mg to 600 mg, as recited in Claim 23. Applicants respectfully reiterate that US 077 expressly recommends a daily administration of up to 10,000 mg of its fatty acid mixture. There further would have been absolutely no motivation to have decreased amount of fatty acid based on the teachings of US 077, US 313 or Lipid Management. Hence the Office Action's urging of "optimization" constitutes an impermissible hindsight analysis.

Applicants further reiterate that the combination likewise fails to teach or suggest advantageous inventive agents in which the cholesterol-reducing active compound is present at 10 to 50% of the dosage which would be recommended in the absence of carob product and n-3 fatty acid, as recited in Claim 24.

Accordingly, Applicants respectfully submit that Claims 1 through 24 are patentable in light of US 313, US 077 and Lipid Management considered either alone or in combination.

Consideration of Previously Submitted Information Disclosure Statement

It is noted that several of the references submitted with Applicants' Information Disclosure Statement filed June 14, 2005 have not been initialed as considered by the Examiner. Specifically, it has been noted that 8 references have not been considered by the Examiner. Applicant's representative notes that a large number of references have been submitted with this application, and regrets any confusion that has arisen due to the volume of references.

In order to facilitate review of the remaining references by the Examiner, a copy of the Information Disclosure Statement and the PTO/SB/08A forms are attached hereto. For further ease of review, the specific references for consideration are listed in bold, as the remaining references have been initialed in previously. Accordingly, it is requested that an initialed copy of the PTO/SB/08A forms indicating consideration of the items in bold be forwarded to the undersigned with the next communication from the PTO. Copies of the cited references were provided at the time of filing the original Information Disclosure Statement, and, therefore, no additional copies of the references are submitted herewith. Applicants will be pleased to provide additional copies of the references upon the Examiner's request if it proves difficult to locate the original references.

CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 24 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

Application No.: 10/539,174
Filing Date: June 14, 2005
Page: 17

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

Cathy Moore

Cathy R. Moore
Reg. No. 45,764

ProPat, L.L.C.
425-C South Sharon Amity Road
Charlotte, NC 28211-2841
Telephone: (704) 365-4881
Fax: (704) 365-4851
Customer No. 38263

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at facsimile number (571) 273-8300 on April 17, 2007.

Claire Wygand

Claire Wygand